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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/776,711
Filing Date: February 12, 2004
Appellant(s): SHAH, MRUGESH

Allen E. White
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/09/2009 appealing from the Office action mailed May 28, 2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1, 3, 9, 11-15, 17, 18 are rejected and pending.

Please note that claim 16 is canceled, even though claim 16 is not listed as canceled in Appendix X of the Appeal Brief.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

WITHDRAWN REJECTIONS

The objection for failure to cite new references in a proper Information Disclosure Statement (per Advisory Action mailed on 07/31/2009) is withdrawn in regards to those references which Appellant provides in the Appeal Brief.

Upon further consideration, copies of references as provided by Appellant as evidence in the Appeal Brief (beginning on p. 39) are considered by Examiner in this Answer.

(7) Claims Appendix

Other than the obvious error in status of claim 16, the examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

Please note that claim 16 is canceled, even though claim 16 is not listed as canceled in Appendix X of the Appeal Brief.

(8) Evidence Relied Upon

Duga et al., The intron-containing L3 ribosomal protein gene (RPL3): sequence analysis and identi¢cation of U43 and of two novel intronic small nucleolar RNAsl, *Biochimica et Biophysica Acta*, vol. 1490 (2000) pp. 225-236.

Carroll, Introduction to recombinant-DNA technology, AM J Clin 1993:58 (suppl) 249S-258S.

Hamme et al., Recent Advances in Petroleum Microbiology, MICROBIOLOGY AND MOLECULAR BIOLOGY REVIEWS, Dec. 2003, p. 503-549 Vol. 67, No. 4.

Izizaki et al., Microbial production of poly-D-3-hydroxybutyrate from CO2, Appl Microbiol Biotechnol (2001) 57:6-12.

Jeffries et al., Metabolic engineering for improved fermentation of pentoses by yeasts, Appl Microbiol Biotechnol (2004) 63: 495- 509.

Lin et al., Ethanol fermentation from biomass resources: current state and prospects, Appl Microbiol Biotechnol (2006) 69: 627- 642.

Pesole, Graziano. What is a gene? An updated operational definition, *Gene*, vol. 417 (2008) pp. 1-4.

Zaldivar et al., Fuel ethanol production from lignocellulose: a challenge for metabolic engineering and process integrationAppl Microbiol Biotechnol (2001)56:17-34.

The American Heritage® Dictionary of the English Language: Fourth Edition. 2000, "petroleum", retrieved 2009, pp. 1-2.

petroleum. (2009). In *Encyclopaedia Britannica*. Retrieved May 24, 2009, pp. 1-18, from Encyclopaedia Britannica Online: http://www.search.eb.com/eb/article-9110438.

coal. (2009). In *Encyclopaedia Britannica*. Retrieved May 24, 2009, pp. 1-18, from Encyclopaedia Britannica Online: http://www.search.eb.com/eb/article-9110442.

Cloning of the Alcaligenes latus Polyhydroxyalkanoate Biosynthesis Genes and Use of These Genes for Enhanced Production of Poly(3- hydroxybutyrate) in Escherichia coli, APPLIED AND ENVIRONMENTAL MICROBIOLOGY, Dec. 1998, p. 4897-4903.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Interpretation

1. As neither the claims nor the specification define the term "biosynthetic petroleum" this is reasonably interpreted to mean petroleum which is produced through biosynthesis, that is, through a process directly involving living organisms which can be microorganisms. American Heritage® Dictionary (retrieved 2009) and Encyclopaedia Britannica (retrieved 2009, “petroleum”) are relied upon for definitions of petroleum. Synthetic petroleum is then reasonably interpreted to be a complex mixture containing multiple components found in petroleum and/or multiple components chemically similar to those found in petroleum.

2. As neither the claims nor the specification define the term "biosynthetic coal" this is reasonably interpreted to mean coal which is produced through biosynthesis, that is, through a process directly involving living organisms which can be microorganisms. Encyclopaedia Britannica (retrieved 2009, “coal”) is relied upon for definitions of coal. Synthetic coal is then reasonably interpreted to be a complex mixture containing multiple components found in coal and/or multiple components chemically similar to those found in coal.

35 USC § 112 Second Paragraph, First Paragraph

New Matter

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 17 and 18 are rejected for reciting new matter of "obtaining a [singular] gene coding a protein capable of said conversion" under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The original specification and original claims describe plural genes capable of said conversion, and not a singular gene capable of said conversion. And while it is noted that the specification does refer to a probe to one of these genes and so refers to a gene of the plural genes which are responsible for the conversion; the specification does not disclose the claimed conversion as through a singular gene. Furthermore, neither the original specification nor the claims disclose a gene *encoding a protein*, much less a gene *encoding a protein capable of the conversion*. And it is noted that every gene need not encode a protein, as Duga et al. (2000) teach genes which do not encode proteins (see 2nd sentence of 5th paragraph on p. 233). And Pesole (2008) similarly teaches that: "A large fraction of genes do not encode for proteins" (see particular point 1 on p. 2). Thus the disclosures of the word "gene" or "genes" by themselves do not provided written support for a specie of a singular gene encoding a protein capable of said conversion. The genus of genes is disclosed, but the specie, of a singular gene encoding a protein capable of said conversion, is not disclosed.

35 USC § 112 Second Paragraph, Second Paragraph

Lack of Enablement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 9, 11-15, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

1. <u>The nature of the invention and breadth of claims</u>

Claims 1, 3, 9, 11-15, 17 and 18 are broadly drawn to methods utilizing a transfected microorganism to produce synthetic products being or resembling the

variable and complex mixtures of petroleum and of coal, each complex mixture containing multiple components of molecules and compounds.

2.The unpredictability of the art and the state of the prior art

There is no support in the prior art or post filing art enabling a transfected microorganism to produce biosynthetic petroleum or biosynthetic coal. as claimed.

One of the related but much simpler art is that of biofuel production. Thus to analyze the instant application against the prior and post filing art, the subset and simpler art of biofuel is reviewed for at least some perspective. It is noted that biofuel in the context of the art is component of biosynthetic petroleum or biolsynthetic coal. However, there is a great deal of unpredictability even in the simpler art of biofuel production. Production of ethanol, a single component biofuel, has received a lot of attention owing to the availability of renewable feedstock from biomass. Yet there is considerable difficulty in making ethanol production a viable process. The state of the art at the time of the claimed invention is revealed by Zaldivar et al. (2001):

"The lack of a microorganism able to ferment efficiently

all sugars released by hydrolysis from lignocellulosic

materials has been one of the main factors preventing

utilization of lignocellulose" (see last sentence on p 17 continued to p. 18).

The post filing related art further confirms the unpredictability of this area. Jeffries et al. (2004) convey in regards to just ethano: "However, the bioconversion of pentoses to ethanol still presents a considerable economic and technical challenge . . .."

(see 3rd sentence on p. 496). Lin et al. (2006) disclose: "In this field, although bioethanol production has been greatly improved by new technologies, there are still challenges that need further investigations. A further understanding of the ethanol fermentation needs to be reached" (see 2nd column, 1st paragraph, last 2 sentences on p. 627). And: "Recently, research has concentrated on the development of improved processes; however, there are still challenges that need further investigations" (see 2nd sentence under the section *Most promising prospects* on p. 635).

In the post filing which is more related but still the far simpler art of alkane production, Van Hamme (Dec., 2003) teaches that not just any microorganism is suitable:

> "As other strains are characterized, it appears that the clustering and regulation of alkane degradation genes varies among the bacteria" (see 1st sentence of paragraph found in the 2nd column on p. 505).

And as seen by the above and further throughout, Van Hamme teaches that clusters of genes need to be used for alkane production (see also Table 1). Van Hamme further teaches that wrong genes are isolated by teaching isolation of a gene later believed not to participate in the main alkane oxidation pathway (see 2nd full paragraph on p. 506). Van Hamme concludes there is much work to be done in general and in regard to gene identification and isolation:

> "In the above cases, there is much work to be done with respect to describing both the genetic systems and the enzymes involved. Even more challenging will be answering questions such as what role these pathways play in environmental remediation, how the different approaches to alkane metabolism

evolve and how are they related, and how well-characterized and novel metabolic pathways can be applied in fine-chemical synthesis" (see 5th paragraph on p. 506).

Van Hamme also provides a summary of the post filing art in Table 3 for petroleum applications showing that all of the known methods have limitations (see last column). In Table 3, Van Hamme teaches that differential amplification during PCR provides no information of activity and no isolates for study, teaches that activity cannot be inferred from presence of genes alone, and the nature of a promoter must known for gene expression. Thus Van Hamme teaches that the expression of acluster of genes necessary for just alkane production, which cluster is but a subset of the genes expected to be necessary for production of biosynthetic petroleum.

Van Hamme teaches that even expression of genes will not necessarily yield activity and thus that simpler methods of alkane production in microorganisms are other than routine and prone to failure, even for those transfected host microorganisms which might initially appear to be suitable:

"To achieve a greater understanding, the molecular biology and biochemistry of the processes need to be understood in detail so that gene expression can be correlated to activity" (see 2nd sentence of the 3rd paragraph on p. 519).

The present claims are not simply to gene expression but to complex and multiple gene activities which are the conversions of feedstocks into biosynthetic petroleum or biosynthetitic coal.

The prior art and the post filing art are not even fully enabled for the simpler arts of single biofuel production or simpler alkane production, especially in regards to

identifying “a” starting microorganism and transfecting “a” host microorganism. No prior or post-filing art has been found which supports enablement of the instant methods.

3. Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied to apply this technology including, the identification of heretofore unknown genes from an unknown starting microorganism which unknown microorganism can convert complex feedstocks into products of complex mixtures; the successful, isolation, transfection, and expression of those multiple unknown genes into a foreign but compatible host microorganism; the variability from source to source of the natural solid fossil fuels and oil tars and other feedstocks for the claimed invention; the ability of a multiple gene transfected host microorganism to adapt and convert these various and disparate feedstocks into complex mixtures of products or analogs found in petroleum or coal; and the conditions of time, temperature, pressure, pH, and others necessary to culture the microorganism to produce the claimed complex mixtures. The time table necessary to achieve efficacious investigation of these parameters would require a very large quantity of experimentation, if in fact, a single transfected microorganism were capable of the claimed conversions. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

4. Working Examples

The specification has no working examples of the claimed invention.

5. Guidance in the Specification.

The specification provides no evidence that a transfected host microorganisms would be able to produce the complex mixtures of products or analogs found in petroleum or coal. The specification does not provide support that a host microorganism would be able to produce such mixtures. Turning to the related art for producing a single product and as found in Table 1 of Ishizaki et al. (2001), the recombinant *E. coli* producing a single product of P(3HB) is not superior to two starting microorganisms *P. extroquens* and *R. eutropha*. Furthermore, Choi et al. (1998) show that several recombinant *E. coli* did not adequately generate a single product of PHB, as shown in Figure 3. Thus in view of these teachings of the difficulty in a transfected microorganism for just producing a single product, there is no expectation of success that a transfected host microorganism will produce the complex mixture of products as claimed. The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the minimally and vaguely disclosed instructions to use the claimed invention.

The specification merely discloses that one follow undisclosed complex and unproven procedures of multiple gene identification and transfection, followed by even the more complex and unproven procedures of selecting and optimizing growth conditions of multiply transfected host microorganism, to produce complex mixtures of individual products by one cultivation of one multiply transfected host microorganism. Furthermore, the specification provides inadequate guidance to identify how many of the genes of any starting microorganism would be need to be transfected. Among the mixtures of products claimed to be produced are multitudes of components most of which are chemically more complex (see definitions of petroleum and coal for the sundry of components of each) than the single product of ethanol, P(3HB), or PHB. The

expectation of the state of the art is that a complex metabolic pathway with several enzymes (and hence several expression genes of the starting microorganism, much more of several regulatory and promoter genes) would be needed to yield the complex mixture of complex products, if this was even feasible. Thorough review of the prior art and post filing art fails to show any enabled teachings of a transfected host microorganism producing the multitude of products found in fossil petroleum and coal mixtures.

Furthermore *In re Goodman* regarding gene expression, which is but one step of the broadly claimed invention, the court held a specification enabling protein expression in dicotyledonous plant cells was enabled, while claims broadly covering any plant cell were held to not be enabled (see *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)). The instant case is to methods of multiple gene transfection and expression in any microorganism for conversion of complex substance into biosynthetic petroleum or biosynthetic coal, without any example or reasonable guidance of this in the specification. No prior art nor any post filing art has been indentified for enabling these methods for a single microorganism specie, much less any microorganism.

6. Level of Skill in the Art

The level of skill in the art is deemed to be high.

7. Conclusion

In the instant case, as discussed above, the factor of unpredictability weighs heavily in favor of undue experimentation in this highly unpredictable art where the variables of transfection of multiple genes into a host microorganism to produce complex mixtures depend upon numerous parameters such as what cluster of genes

may be needed, under what conditions the feedstock might be converted into mixtures, how the transfected microorganism is to be introduced into the feedstock and how its growth is to be maintained, and what the acceptable limits are of temperature, pressure, aeration or lack of aeration, and degree of mixing. Further, the prior art, the post filing art, and especially the instant specification provide insufficient guidance to overcome the art recognized problems in the use of producing the complete range of products found in petroleum or coal by multiple genes from one specie of starting microorganism transfected into one other specie of host microorganism. Thus given the broad claims in arts whose nature is identified as unpredictable, the large quantity of research required to define the unpredictable variables, the lack of guidance provided in the specification, the absence of a working example, and the negative teachings in the prior and post filing art even for conversion to a single product balanced only against the high skill level in the art; it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

(10) Response to Argument

A. Statement by Appellent of Facts (see Appeal Brief pp. 5-8)

Facts agreed to and not agreed to by Examiner, as follows.

[01] Zaldivar, et. al. ("Zaldivar"; Exhibit A) is a reference describing the state of the art for commercial bioethanol production using a lignocellulose feedstock. See, e.g., the Abstract; page 28, right column, last full paragraph.

Examiner agrees.

[02] Zaldivar discloses several microorganisms capable of metabolizing lignocellulose derived sugars into bioethanol. See, pages 21-23 (Broad substrate utilization range).

Examiner agrees.

[03] Zaldivar also describes successful metabolic engineering efforts to increase the efficiency of such utilization toward the goal of commercial production. Id., summarized at Table 2.

Examiner agrees.

[04] Zaldivar discusses an example of an unexpected failure of a genetic manipulation of a bioethanol microorganism where the result in industrial scale processes did not match that seen at the laboratory scale. See page 27, 2nd col., 1 st full paragraph.

Examiner disagrees as this conclusion is taken out of context. Zaldivar teaches:

This undesirable and unexpected result emphasized that: (1)

the cell is a complex network of regulatory mechanisms,

just partially elucidated, **which makes it difficult to predict**

the consequences of the genetic changes introduced (emphasis by Examiner). Examiner further notes that these “genetic changes" are just for production of one product which is ethanol.

[05] Lin and Tanaka ("Lin"; Exhibit B) is a broad overview of bioethanol production from sugars, starches and cellulosic materials. See page 628, 1 st col., 2nd paragraph.

Examiner agrees.

[06] Jeffries and Jin ("Jeffries"; Exhibit C) is focused on metabolic engineering of yeast to utilize pentose sugars in bioethanol production to achieve commercial competitiveness of the process where lignocellulose is the feedstock. See Abstract.

Examiner disagrees with the characterization of “focused”.

[07] van Hamme et al. ("van Hamme"; Exhibit D) reviews the advanced state of knowledge on the genes and genetic circuits of alkane metabolizing microorganisms. See pages 506-514.

Examiner disagrees with the characterization of “advanced”.

[08] The Application as filed directs one of skill in the art to exemplary microorganisms and culturing conditions found in the cited background reference WO0246446. Application as filed, page 1, lines 6-20.

Examiner disagrees with the characterization of "exemplary".

[09] Kurashkov, et al. ("Kurashkov"; Exhibit E) discloses microorganisms capable of making biosynthetic petroleum and their culturing conditions. See Office action issued 22 Jan. 2007, page 15, 3rd paragraph.

Examiner disagrees with the characterization of "making biosynthetic petroleum". Examiner notes that Kurashkov teaches petroleum hydrocarbons and individual hydrocarbon fractions of solid fossil fuels, which are respective subsets of petroleum and solid fossil fuels.

[010] Martin S. Cohen and Peter D. Gabriele ("Cohen"; Exhibit F) show additional fungal microorganisms capable of converting coal into biosynthetic petroleum and their culturing conditions. See, e.g., the Abstract.

Examiner disagrees with the characterization of “biosynthetic petroleum".

[011] Appellant requests the Board take judicial notice of the existence of extensive technology for measuring and identifying the chemicals of petroleum. The Examiner refuses to acknowledge or concede that technology existed as of the priority date for qualitative or quatititative measurements of petroleum compounds. Advisory action mailed 31 July 2009.

Examiner disagrees and considers technological references properly provided. Examiner has provided and acknowledged extensive technological citations of petroleum and coal. See section 8 above.

[012] The specification expressly identifies a subtraction hybridization/screening approach for isolating the genes. See page 3, line 19 to page 6, line 4 of the Application as filed.

Examiner disagrees with the characterization of “expressly identifies". Examiner maintains that the specification is not enabled for expressly identifying the claimed genes. No evidence has been presented that the claimed genes exist.

[013] Expression screening and other standard molecular biology techniques for screening and isolating genes for proteins having specific biochemical activities were well established in the art as of the effective date of the Application. See, e.g., King et al., page 1, 2nd paragraph ("King"; Exhibit G).

Examiner disagrees as this is oversimplified; King in fact teaches a single gene can be isolated from multiple genes when a desired/specific biochemical activity is expressed and present; if the gene is not expressed as a protein or the biochemical activity of the protein is not present, the single gene is not identified.

[014] The state of the art of synthetic biology, as it applies to microorganism based biofuels, was adequately developed as of the priority date of the instant application to enable one of ordinary skill in the art to transfect multiple genes to work together to produce complex biosynthetic pathways. See Kalscheuer, Abstract (Exhibit H); WO2007/0136762, Examples 2-8, Pages 51-57 (Exhibit I).

Examiner disagrees with the characterizations of “biofuels” and “complex biosynthetic pathways".

[015] The state of the art was enabling for both identification of microorganisms capable of producing biosynthetic petroleum and identification of the genes responsible for this activity. See Dennis; (Exhibit J).

Examiner disagrees with the characterization of “capable of producing biosynthetic petroleum and identification of the genes responsible for this activity ".

[016] There was a post-filing reduction to practice of the claimed subject matter. See Savage (Exhibit K); Ayres (Exhibit M); Plenty (Exhibit L).

Examiner disagrees as this is conclusory.

[017] WO2007/0136762 corresponds the LS9 reduction to practice supra. See WO2007/0136762 (Exhibit I).

Examiner disagrees as this is conclusory.

[018] WO2007/0136762 applies molecular biology and microbiology techniques which were within the skill in the art prior to the effective date of the Application. WO2007/0136762, Examples 2-8, Pages 51-57 (Exhibit I).

This alleged statement is not addressed for being incomplete, as it is unknown to what the techniques are being applied to.

A. Appropiate Legal Standard

The standard which Examiner applied in the Enablement rejection is that of the *Wands* factor analysis as given above and which is proper.

Appellant appears to have misinterpreted Examiner's Enablement rejection in assertions that commercial success and industrial scale production are requirements of the rejection. Examiner makes no requirements of commercial success or industrial production. It is simply that in the art of petroleum and coal production, commercial success and industrial production are obvious goals. This is true as well for the related art of biofuel production.

Petroleum, coal, and biofuels are obviously of commercial interest as found directly or indirectly in nearly every cited reference, whether cited by Examiner or Appellant. Appellant's specification itself discloses: "The invention relates to a method of making microorganisms capable of **producing** petroleum from coal, or wood or certain other fossil fuels, or raw materials including turf, grass, glucose, rubber, sapropel, sapropelites, slates and wood, in a highly efficient, **commercially viable manner**" (see paragraph 0003, emphasis by Examiner). Thus commercial success or

viability, while not relied upon in the enablement rejection is a topic expected to be routinely encountered in the art and related arts.

Appellant also makes arguments regarding claims, particularly to but not specifically indentified as original claim 8 which recited "commercial production of petroleum", and responds to past rejections by Examiner. However, as claim 8 is now canceled, Examiner does not address the arguments regarding claim 8.

And noting at this point that although it is not specifically the claimed subject matter, Examiner has cited related art of converting substances into biofuel in order to provide technical background on the lack of enablement of the far more complex biosynthetic production of petroleum and coal (the claimed subject matter).

Biofuel as presented throughout the cited art is not biosynthetic petroleum and is not biosynthetic coal.

Biofuel is not claimed.

Unfortunately and as given more below, there is no prior art or post-filing art disclosing biosynthetic production of petroleum and coal by a multiple gene transfected host microorganism. Thus in order to analyze the instant claims for enablement, the related art of biofuels is relied upon.

A. Detailed *Wands* Factor Analysis

1. The nature of the invention and breadth of claims

Appellant concurs with the broad nature of the claims.

2. Unpredictability of the Art and the State of the Art

Zaldivar (2001) discloses fuel ethanol production. Although Zaldivar does not literally does disclose "biofuel", ethanol in context here is a biofuel. However Zaldivar does not disclose or suggest biosynthetic petroleum nor biosynthetic coal. Zaldivar is cited in the enablement rejection, owing to the teachings that of the difficulties of methods for the simpler but related art of converting lignocellulose by a microorganism to a single product, which is ethanol. Thus the teachings of Zaldivar provide evidence that the production of a single fuel component which is ethanol is other than routine, thus revealing that the claimed invention to complex mixtures of multiple components is even far more than routine, if indeed, possible at all.

Appellant argues that Van Hamme teaches the need to understand detailed enzyme kinetics and which understanding is not required to have methods of producing biosynthetic petroleum or coal. Van Hamme encourages but does not insist upon the more complete and detailed understanding of enzyme processes to produce alkanes. More relevantly, Van Hamme teach identifying and/or modifying microorganisms to produce alkanes, alkanes being a subset of biosynthetic petroleum or coal, and that this must be done with the proper but not obvious microorganisms and that unguided transfection and expression of genes does not guarantee success. This is given more fully in the rejection above.

3. Quantity of Experimentation

Appellant again argues that commercial success is not necessary for enablement. Examiner agrees.

Appellant further argues that the teachings of Zaldivar are not directly encompassed by the instant claims in regards to limitations of biosynthetic petroleum and biosynthetic coal. Examiner agrees as the claims recited very complex mixtures which are biosynthetic petroleum and biosynthetic coal; and the related art of Zaldivar teaches but a single product of ethanol, which at least is an analog of components found in petroleum or coal. The art of Zaldivar is thus related to the art of the instant claims and points out the difficulties and non routine nature, commercial success aside, for production of ethanol by microorganisms. Thus and as there is not directly relevant art enabling the complete and instant claims, the related prior of Zaldivar is correctly cited for analysis of enablement.

Appellant argues similarly that the alkanes of Van Hamme are not components of coal or petroleum. However van Hamme specifically teaches petroleum alkanes are (see first full sentence on p. 522). Thus and although Hamme does not teach production of biosynthetic petroleum or coal, van Hamme does teach the lack of guarantee of success in biosynthetic production of just a subset of those mixtures which are alkanes. Furthermore, Hamme teaches that genes to utilized need to be known in order to successfully produce just the relatively limited components of alkanes. The instant application does not identify a single specific gene for the claimed conversion fo feedstocks into biosynthetic petroleum or biosynthetic coal.

4. Working Examples.

Appellant agrees that no working example is provided in the specification. No working example is provided of identification or transfection of a single gene or of

productions of any feedstock into even just one component of biosynthetic petroleum or biosynthetic coal.

5. Guidance in the Specfication.

Appellant argues there is no need to provide well known material in the specification or by providing relevant copies of such. Appellant has not provided copies of relevant sections but argues that Examiner should consider the Handbook of Petroleum Analysis.

In contrast, Examiner has provided extensive background on petroleum and coal as given in section 8 above for Appellant's consideration and review. In those references both petroleum and coal are revealed as complex mixtures of several classes of compound and molecules with the mixtures from different sources often varying considerably.

Appellant argues that general arts of petroleum and coal are quite extensive and Appellant need not provide all of it or even a majority of it. However, it seems to be in Appellant's interest to put before Examiner that which would support the enablement of the instant methods as claimed. No prior art has been identified which supports enablement of the instant claims. If there is some pertinent reference in the general relevant arts supporting Appellant's position, such should be properly presented for consideration.

6. Level of Skill in the Art.

Appellant agrees that the level of skill in the art is very high.

7. Conclusion

Examiner has cited related art in support of the lack of enablement as no prior art or post-filing art was found which supports enablement of the instant claims. Thus the rejection of the claims for lack of enablement is proper. Examiner respectfully requests that the rejection be maintained. The lack of art either pre-filing or post-filing of the instant application which supports enablement of the instant claims is evidence that the instant claims are not enabled.

C. Appellant Evidence of Enablement

Examiner maintains that the burden of establishing unpatentability has been met as given above and as follows in response to Appellant's further arguments.

1. Claim 1

a) isolating a starting microorganism capable of said conversion;

Appellant refers to bioprospecting for a single enzyme activity as an example of bioprosecting in general. However, Appellant has provided no guidance and no example of bioprospecting identifying a starting microorganism capable of converting complex feedstocks into biosynthetic petroleum or biosynthetic coal. Nor has such a starting microorganism been identified by the related art.

Examiner disagrees that the teachings of Kurashkov enable the instant claims, even by the art of bioprospecting. Examiner notes that Kurashkov teaches petroleum hydrocarbons and individual hydrocarbon fractions of solid fossil fuels, which are respective subsets of petroleum and solid fossil fuels. The instant claims broadly recite conversion of feedstocks into the complex mixtures of biosynthetic petroleum and

biosynthetic coal. Thus any bioprospecting of Kurashkov has not identified the claimed starting microorganism capable of the conversion the instant claims.

It is further noted that the former rejection over Kurashkov of previously recited claims has been withdrawn. The claims have since been appreciably amended.

b) isolating from the starting microorganism the genes responsible for the conversion ability;

Appellant argues that expression cloning was well known in the art. However and as evidenced and taught by van Hamme, the isolation/identification, cloning, expression, and achievement of activity of a cluster of genes for producing just multiple alkanes was not routine, and could not use just any starting microorganism or any host microorganism, as already given above. Thus the type of conversion and steps of isolation/identification, cloning, expression, and achievement of claimed activity/conversion ability of a cluster of genes into any microorganism was not known in the art. And no evidence has been found that is even identified in the post-filing art. Thus, to be enabled these unknown steps in the specification must enable one skilled in the art to use the claimed invention by providing the guidance to do so. The prior art does not provide this needed guidance.

c) transfecting the genes into a host microorganism, and

Appellant's arguments here are directed to enabling biofuels but the claims recite not biofuels but biosynthetic petroleum and biosynthetic coal. The art of biofuels is an art related to the art of the instant claims, and Examiner has augmented explanation of this above which hopefully further clarifies the rejection. Largely, it is the post filing

related art where multiple gene transfection in related arts is beginning to be explored. The post filing and related art of van Hamme newly reports limited success along with failures and limitations in identifying and transfecting clusters of genes for complex pathways to alkanes, which although the pathways arecomplex are reasonably considered to be far simpler than far more complex pathways which would be required for the instant claims.

d) combining the host microorganism with the solid fossil fuels or oil tars under conditions suitable for the conversion of the solid fossil fuels or oil tars into biosynthetic petroleum.

Appellant argues that the foregoing step was known. However Appellant's citations do not provide support for biosynthetic petroleum but rather individual components or much smaller subsets, at best, of biosynthetic petroleum. Furthermore, the later and post-filing art of van Hamme teaches that formerly-believed conversions by degradation of petroleum by microorganisms was in reality also due to evaporation, dispersion, and photooxidation (see 3rd paragraph on p. 522). Van Hamme further teaches a microbial population is needed for degradation of petroleum, that is, that "a" microorganism would not be sufficient (see 4th full sentence on p. 523). And the degradation of van Hamme is also subset of the conversion needed which produces only a subset of petroleum components. Thus the later publication of Hamme at least suggests a more critical consideration of what was earlier reported in the related arts. This includes a critical consideration of Kurashkov's teaching of conversion of feedstock into just limited components of petroleum or solid fossil fuels.

2. Claim 11

Appellant argues that Dennis teaches “biosynthetic petroleum” but again Dennis at best teaches only a subset of petroleum/petroleum analogs which is hydrocarbons and the non petroleum product which is CO (see Title and entire article).

Appellant argues that the post-filing art of Plenty enables the instant claims for biosynthetic petroleum. But to the contrary, Plenty teaches a transgenic microorganism, LS9, which does not even produce conventional crude oil, much less produce biosynthetic petroleum. LS9 produces non conventional and simpler oil, from which only simpler fuel, or certain products of petroleum, can further be made as noted:

> “**Conventional crude oil can contain thousands of types of molecules**--that's why it's called "**crude**"--but **LS9's will have only about ten**, which Pal says is ideal: The company's oil will have the molecular diversity necessary to make a number of fuels and petroleum products but will be free of unwanted chemicals that can muck up engines. It's "a pretty optimal solution," he [Pal] says” (emphasis by Examiner, see 3rd full paragraph on p. 2).

Savage further confirms that LS9 produces hydrocarbons which are biofuel, and not biosynthetic petroleum (entire article, especially the title and the 1st sentence on p. 2). Ayres does relay a comment of “renewable petroleum” (see 3rd paragraph on p. 1) but in context this is understood as being the simple biofuel produced by LS9 and not a complex mixture of components to be found in biosynthetic petroleum.

Furthermore, the non-technical articles of Plenty , Savage, or Ayres do not provide the reasonable and necessary guidance which the art requires to enable production of biosynthetic petroleum or biosynthetic coal.

Appellant then argues that WO 2007/136762 by Keasling et al. is the post-filing art which supplies enablement of the LS9 microorganism referred to by Plenty, Savage, and Ayres. But Keasling teaches in technical accordance with the related arts that the invention is to biofuels or biodiesels derived solely from identified fatty acid pathways (see 3rd paragraph under background), and thus is not directed to biosynthetic petroleum or biosynthetic coal. Furthermore for production of the biofuels, Keasling claims specific and limited microorganisms, identifies the genes needed often by specific nucleic acid sequences, and identifies the structures of limited and specific molecules of the biofuels (see claims), and teaches the specific aspects required for transfection and production at length in the working Examples 1-12 . In other words the post-filing and detailed disclosure of Keasling reveals that the steps of the instant claims were other than routine. And the molecules produced by Keasling are and at best but far simpler subsets of the thousands of types of molecules to be found in biosynthetic petroleum, as also conveyed by Plenty, Savage, and Ayres.

Appellant argues that these specific and extraordinarily detailed disclosures of Keasling for producing a comparatively and expressly disclosed simple biofuel would enable the instantly and broadly claimed invention by making up for the lack of guidance in the instant specification. Examiner disagrees and contends that even the specific and extraordinary disclosures of Keasling were not readily available or realized by one

of skill in the art at the time of the claimed invention. Appellant has not presented evidence to the contrary. But even if the disclosures of Keasling were available at the time of the claimed invention, they would not have enabled one of skill in the art to produce biosynthetic petroleum or biosynthetic coal, as claimed.

D. Conclusion

Based on the foregoing, Examiner requests that the rejection be maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Mark Staples/

Examiner, Art Unit 1637

June 17, 2010

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